

REMARKS

Claims 1-7 are pending in the present application.

The rejection of Claims 1-2 under 35 U.S.C. §102(e) over Hatada et al is obviated in part by amendment and traversed in part.

The rejection over Hatada et al as anticipating Claim 1 is without merit. In making this rejection, the Examiner alleges that Hatada et al disclose a sequence with 97.5% homology to SEQ ID NO: 1. However, this sequence of Hatada et al does not meet the limitations of Claim 1, which requires that the sequence be SEQ ID NO: 1, with the possible specifically recited mutations. As such, Claim 1 cannot be anticipated since all the elements of the claim are not disclosed by Hatada et al.

Turning to Claim 2, the Examiner has held that species (f) is met by the Hatada et al disclosure. In making this assertion, the Examiner appears to recognize that the elected species (species (d)) is free from the art of record and, therefore, has expanded her search to other species for which Applicants thank the Examiner. However, the claim as originally presented (i.e., 80% homology) is held to read on the art of record. To this end, Applicants have amended Claim 2 to limit the scope of homologs to those having at least 98.1% homology to SEQ ID NO: 1. Therefore, Hatada et al fails to anticipate the invention of amended Claim 2 since the sequences disclosed therein do not fall within the scope of present Claim 2.

Applicants request withdrawal of this ground of rejection.

The rejections of Claim 2 under 35 U.S.C. §112, first paragraph (written description and enablement), are obviated by amendment.

The Examiner has rejected Claim 2 based on the breadth of the permissible homologs of the claimed amino acid sequence of SEQ ID NO: 1. Indeed, it is the current trend in U.S. patent practice to narrow the permissible scope of homologs. However, Applicants direct the Examiner's attention to a recent decision by the U.S. PTO's Board of Patent Appeals and Interferences (*Ex parte Bandman*, copy **enclosed herewith**) that held that claims to polypeptides and/or polynucleotides sequences that are at least 95% identity to the disclosed sequence are adequately described and enabled when the specification describes the nucleotide and amino acid sequences. As in *Ex parte Bandman*, the present application fully discloses the polynucleotide of SEQ ID NO: 2, which includes the polypeptide of SEQ ID NO: 1, and provides support for homologs of at least 98.1% (see pages 6-8 and original Claims 1 and 2). As such, the specification adequately meets the current standard of the Office and should be entitled to sequences that are at least 95% homologous to SEQ ID NO: 1. Indeed, the Examiner recognizes that the scope of homology defined by 98% is enabled in her comments relating to the enablement rejection (see page 10 of the Office Action mailed April 18, 2006).

Withdrawal of these grounds of rejection is requested.

The rejection of Claim 2 under 35 U.S.C. §112, second paragraph, is respectfully traversed.

The Examiner has objected to the use of the term "homology" in Claim 2 as being indefinite, alleging that "homology refers to ancestral or evolutionary linkage, not percent sequence identity that is calculated by a mathematical algorithm." This allegation is not supported by any references or further explanation. Applicants further submit that the term "homology" has been widely recognized by the Office to be appropriate in claims to

polynucleotide and amino acid sequences. In fact, a key word search of the USPTO Patent Full-Text and Image Database from 1976 to present using the search terms “protein” and “homology” as claim terms resulted in 381 patents. Five representative examples that have the same contextual usage of the term “homology” as the present application are: US 6,995,250, US 7,026,151, US 7,029,860, US 7,029,896, and US 7,049,860.

Moreover, Applicants submit that “homology” is defined on page 8 of the specification with reference to an algorithm for determining the same. Applicants wish to remind the Examiner that: “Applicants are their own lexicographer” (MPEP §2173.01). MPEP §2173.01 also states that Applicants “can define in the claims what they regard as their invention essentially in whatever terms they choose so long as the terms are not used in ways that are contrary to accepted meanings in the art.” Further, definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made (MPEP §2173.02).

Applicants submit that page 8 of the specification evidences the content of the application disclosure, while the aforementioned US patents evidence the teachings in the art and the interpretation of the skilled artisan. As such, Applicants submit that the term “homology” in Claim 2 is not indefinite.

In view of the foregoing, withdrawal of this ground of rejection is requested.

The rejection of Claims 1-2 under 35 U.S.C. §101 is believed to be obviated by amendment.

The Examiner has held that the original "alkaline protease" claims read on products of nature. As such, the Examiner has recommend that Applicants add the term "isolated" to the preamble of these claims. Consistent with the Examiner suggestion, the claims have been amended accordingly.

Withdrawal of this ground of rejection is requested.

The objection to Claim 1 (and Claim 2) is believed to be obviated by amendment.

The Examiner has objected to the language of Claim 1 (and Claim 2). In addition, the Examiner has proposed an amendment that she believes would overcome this ground of objection. At least as far as Claim 1 is concerned, this amendment appears to be acceptable. However, with respect to Claim 2, it is important that the phrase "or at positions corresponding to these positions" be maintained. As the skilled artisan would readily appreciate, within the scope of 98.1% homology to SEQ ID NO: 1 there may not be a one-to-one positional alignment (for example, residue 15 in the homologous polypeptide may not be residue 15 in SEQ ID NO: 1 and when the sequences are aligned it is determined that residue 17 in the homologous polypeptide "corresponds" to residue 15 in SEQ ID NO: 1).

In view of the foregoing, Applicants request withdrawal of this ground of objection.

The objections to the specification and Abstract are believed to have been obviated by amendment.

The Examiner has objected to the specification for several reasons of formalities. Specifically, the Examiner has requested that Applicants: (a) correct a typographical error on page 15, (b) expand the Brief Description of the Drawings, (c) add the cross-reference to

related applications, and (d) capitalize the tradenames that appear in the specification and add the corresponding generic terminology. The Abstract has also been objected to.

Applicants have made the appropriate amendments to address these criticisms. As such, withdrawal of these grounds of objection is requested.

Finally, the objection to the disclosure as failing to comply with the Sequence Listing rules is obviated by amendment and submission of the substitute Sequence Listing herewith.

Applicants submit herewith a Sequence Listing and a corresponding computer-readable Sequence Listing. The sequence information recorded in the corresponding computer-readable Sequence Listing is identical to the paper copy of the Sequence Listing. Support for all of the sequences listed in the Sequence Listing is found in the present application. The specification has been amended to include sequence identifiers. No new matter has been introduced by the amendment to the specification, the submission of the Sequence Listing, and the corresponding computer-readable Sequence Listing.

Accordingly, Applicants submit that the present application is now in condition for allowance. Early notification of such action is earnestly solicited.

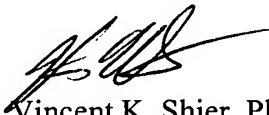
Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.  
Norman F. Oblon

Customer Number

**22850**

Tel: (703) 413-3000  
Fax: (703) 413-2220  
(OSMMN 08/03)



Vincent K. Shier, Ph.D.  
Registration No. 50,552